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**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q57234

Yoshihisa NISHIBE, et al.

Appln. No.: 09/446,276

Group Art Unit: 1615

Confirmation No.: 2101

Examiner: Amy E. Pulliam

Filed: December 21, 1999

For: **PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA**

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, as is a copy of a Communication from a foreign patent office citing the documents.

The present Information Disclosure Statement is being filed after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore Applicant is filing

INFORMATION DISCLOSURE STATEMENT  
U.S. Appln. No.: 09/446,276

ATTY DKT Q57234

concurrently herewith a Statement Under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant submits partial translations of the Dictionary of Food Additives (Ref. No. 3 on page 2 of the foreign Communication) and Textbook of Pharmacology (Ref. No. 4 on page 3 of the foreign Communication) listed under Non-Patent Literature Documents and U.S. Patent No. 5,942,242, which is an English language equivalent of JP 9-25238 (Ref. No. 2 on page 2 of the foreign Communication). Ref No. 1 listed on page 2 of the foreign Communication was previously cited in the IDS filed on March 30, 2001, and Ref Nos. 5 and 6 were previously cited in the IDS filed on January 16, 2004, for the above-identified application.

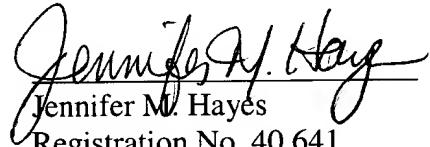
The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



Jennifer M. Hayes  
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SUGHRUE MION, PLLC  
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WASHINGTON OFFICE  
23373  
CUSTOMER NUMBER

Date: July 16, 2004



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q57234

Yoshihisa NISHIBE, et al.

Appln. No.: 09/446,276

Group Art Unit: 1615

Confirmation No.: 2101

Examiner: Amy E. Pulliam

Filed: December 21, 1999

For: PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA

**STATEMENT UNDER 37 C.F.R. § 1.97(e)**

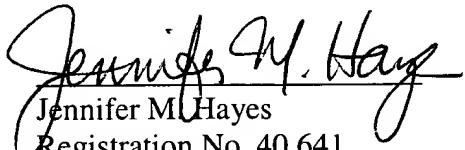
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The undersigned hereby states, upon information and belief:

That each item of information contained in the Information Disclosure Statement filed concurrently herewith was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of said Information Disclosure Statement.

Respectfully submitted,

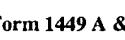


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 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>		<i>Complete if Known</i>															
Sheet	1	of	1														
<table border="1"> <tr> <td>Application Number</td> <td>09/446,276</td> </tr> <tr> <td>Confirmation Number</td> <td>2101</td> </tr> <tr> <td>Filing Date</td> <td>December 21, 1999</td> </tr> <tr> <td>First Named Inventor</td> <td>Yoshihisa NISHIBE</td> </tr> <tr> <td>Art Unit</td> <td>1615</td> </tr> <tr> <td>Examiner Name</td> <td>Amy E. Pulliam</td> </tr> <tr> <td>Attorney Docket Number</td> <td>Q57234</td> </tr> </table>				Application Number	09/446,276	Confirmation Number	2101	Filing Date	December 21, 1999	First Named Inventor	Yoshihisa NISHIBE	Art Unit	1615	Examiner Name	Amy E. Pulliam	Attorney Docket Number	Q57234
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Attorney Docket Number	Q57234																

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Dictionary of Food Additives, 1 <sup>st</sup> edition, p. 49-50 (1994), and partial translation	partial
		Textbook of Pharmacology, 2 <sup>nd</sup> edition, p. 319-320 (1987), and partial translation	Partial
		Japanese Office Action	

**Examiner Signature** \_\_\_\_\_ **Date Considered** \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or in the comment box of this document. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to indicate here if English language Translation is attached.